BVE · Godesberger Allee 142-148 · 53175 Bonn

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
USA

via email: fdadockets@co.fda.gov

Bundesvereinigung der Deutschen Ernährungsindustrie e. V.

Federation of German Food and Drink Industries

Godesberger Allee 142-148
D-53175 Bonn
Telefon 0228-30829-0
Telefax 0228-3082999
bve@bve-online.de
www.bve-online.de

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Re: Notice of Proposed Rulemaking Under the Public Health Security and Bioterrorism Preparedness Act of 2002

- **Docket No. 02N-0276 (Section 305 – Registration)**
- **Docket No. 02N-0278 (Section 307 – Prior notice)**

Comments of the Federation of German Food and Drink Industries (BVE)

Dear Sir or Madam,

the Federation of German Food and Drink Industries (BVE) welcomes the opportunity to provide comments on the FDA proposals to implement Sections 305 and 307 of the Bioterrorism Act.

BVE is the leading association of the food and drink industry in the Federal Republic of Germany, for the area of economic and trade policy. It represents the interests of Germany's fourth-largest industrial sector, an industry that comprises an especially large number of small and medium-sized companies and that produces a broad range of wholesome, high-quality products. The food and drink industry exports almost 20% of its produce to foreign countries, mainly within the EU and Europe. The US is its largest single overseas export market, with an export volume of roughly US-$ 800 bn or 3.2% of total German food and drink exports. Over the last years, trade has developed very favourably—in 2002 alone, the volume of German food and drinks exported to the US rose by 7.4%. At the same time, imports originating in the US rose by 7.7% to almost US-$ 700 bn.

However, this positive trend risks to be disrupted by the proposed rulemaking of FDA.

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In principle, BVE considers legitimate the US objective to protect consumers against the risk of intentional adulteration or any other sort of risks concerning products that are marketed to US consumers.

However, BVE is concerned about the impact the proposed measures may have on trade, notably where these could add cost, delay and uncertainty for exporters. BVE considers that the proposed measures to be applied to food importers—notably the registration requirement of Section 305 of the Act—and imports into the US—the prior notice requirement of Section 307—will impose heavy and costly burdens upon German and EU exporters and will act as a clear non-tariff barrier. Small and medium sized companies in particular risk being prevented from continuing to export to the US, especially where the new regulations and the administrative burdens imposed on them would render their exports too costly to be economically viable. In our view, FDA seems to have significantly underestimated both the costs of registering and of giving prior notice to FDA.

The US law also appears to contradict attempts made within the WTO in the context of current negotiations to agree on measures that would facilitate trade through the simplification and streamlining of customs procedures.

Finally, further to the rule-making on the Bioterrorism Act, BVE is concerned about the other new US rules relating to international trade which were also inspired by the aim to increase security and prevent terrorist attacks—namely the Container Security Initiative (CSI) and the Customs-Trade Partnership Against Terrorism (C-TPAT). It is BVE´s suggestion, therefore, to create links between the different projects in that compliance with one automatically counts as compliance with others. For example, shipments originating in a CSI harbour could be exempt from the prior notice at the FDA. Or, companies taking part in the C-TPAT could be exempt from the proposed keeping of records and from having to register explicitly with the FDA (this could be done internally between US agencies). To be sure, on top of all this, there are already strict EU regulations that member companies need to comply with before products leave our shores.

BVE—as a member of the Confederation of EU food and drink industries (CIAA)—fully endorses the CIAA's comments on the proposed rulemaking which was sent to FDA recently. In addition to that, the German Food and Drink Industry wishes to spell out its specific concerns with the proposed measures. You will find enclosed further more specific and detailed comments on certain provisions of the proposed laws which should be simplified or amended in order to relieve some of the burden that German exporters will have to bear.

Thank you for taking our concerns into consideration.

Yours sincerely,

Dr. Sabine Eichner Lisboa
Managing Director

2 Annexes enclosed

Annex 1

Specific remarks and demands for amendments to the FDA proposals on registration of food facilities (Section 305 of the Bioterrorism Act 2002)

Docket No. 02N-0276

US and foreign facilities will have to register between 12 October and 12 December 2003 to help counteract terrorist threats or outbreaks of food-borne illness, by determining the source and cause of a problem. The draft law raises a number of concerns:

- The obligation to have a single agent in the US is a matter of serious concern especiallly for small and medium sized companies (SMEs). This requirement does not acknowledge the commercial reality of some German and European producers, who often deal with two or more importers in the USA—because of geographical or product differences—or who operate using different importers case-by-case. It is also possible that products sold to German food retailers are shipped by the retailer to export destinations not previously known to the producer, for example if the retailer regularly re-stocks its outlets in several English-speaking countries from products bought in bulk from German producers. In these cases it is not trivial to assign a single US importer or broker as agent. For the purpose of registering with FDA the necessitiy of having an US agent is not appearant. Registering can be accomplished—via the internet—without any US party other than FDA involved.

- As a matter of fact, as recognized in the notification text, a number of German exporters do not have an agent yet and the additional cost a company will incur for the hiring of an agent may lead to the decision not to enter registration. In practice, SMEs will be most affected by the measure. BVE considers that this part of the text interferes in commercial relations between companies. It should not be compulsory to hire an agent and hence procedures should be made easier for exporters who do not have an agent.

- In many cases, German companies send finished or semi-finished goods or even raw materials only to their own subsidiaries in the US, where these products undergo a more than minimal further processing. The US subsidiary is therefore ultimately responsible for bringing these products into the food chain in the US. Hence, their foreign parent company should not have to register with the FDA.

- In some cases, the foreign facility only packs raw materials previously bought (some on international markets) in order to send them to its US subsidiary for final processing. Under the proposed provision, not only this facility, but also all of its suppliers would have to register with the FDA. Where a company sends unprocessed or minimally processed goods to its own US subsidiary, it is often impossible or at least very difficult to ensure that all of the sending company's suppliers were registered with FDA, as the draft rulemaking stipulates. Still, the

economic consequences of a failure to register for one of the suppliers, i.e. a product detention at the port of entry, would in most cases have to be borne by the sender. In order to avoid these consequences the sending facility would have to make sure that all of its suppliers are registered with the FDA. This would be an extreme administrative burden. Some of the suppliers may be located in other third countries, and it may be very difficult to ensure their registration, to oblige them to register and, lastly, to hold them responsible for not registering, given various and possibly complicated legal systems of the countries in question. Again, this should not be necessary as the US subsidiary's registration should suffice.

- Companies exporting to the US with more than one production site face difficulties in interpreting the rules on registering. Even though FDA has made an effort to define this, it should be spelt out even more clearly which companies or sites have to register. In BVE's opinion it should suffice that solely the parent company registered itself once-and-for-all if it centrally manages all of its prodution plants' exports to the US and takes the responisibilty for these trade flows. In this case it is not necessary for FDA to know the actual production sites of the goods offered for importation. Rather, if a problem is suspected, it is sensible and sufficient for FDA to contact the appropriate responsible person in the foreign parent company who coordinated the shipment.

- BVE also requests consideration and clarification of the requirements for limited quantities of samples (e.g. for market testing or tasting. Any requirement to comply with the registration provision before their importation could create a serious impediment to the introduction of new products or promotion of products already in the market.

- Last but not least, in order to get the system operational step-by-step and not disrupt trade flows a period of exemption from prosecution should be foreseen for operators who do not register correctly (or at all) in time.

Annex 2

Specific remarks and demands for amendments to the FDA proposals on prior notification (Section 307 of the Bioterrorism Act 2002)

Docket No. 02N-0278

The importer or the purchaser will have to provide for prior notice due by noon of the calendar day before the article of food arrives at the port of entry but not earlier than five days before arrival. This provision will impose heavy administrative burdens on operators as a prior notification will have to be submitted for each different product in a shipment, and for each different format / packaging of the same product. BVE wishes to make the following specific comments:

- BVE deeply regrets the FDA's failure to coordinate the prior notice requirement with existing customs measures, resulting in duplication and complication of systems. US Customs already receive notice of the arrival of each ship and its manifest well in advance of the ship´s arrival. Most of the data required for the prior notice are provided to Customs. There should be no need for the FDA to require duplicate information already obtained by Customs. A close coordination between the FDA and US Customs Service is necessary to avoid redundant regulations.

- On this same point, the prior notice provision is similar to the "24-hour" rule of the Container Security Initiative. Here again BVE would stress that systems must be integrated rather than duplicated. It is conceivable that the notice given to US Customs within the 24-hour-rule of the CSI is passed on to FDA automatically. In some cases this information would be available earlier than five days before the arrival of the shipment in the port of entry to the US. The Act does not preclude the possibility to supply this information earlier than foreseen in the proposed FDA regulation. Thus BVE requires FDA to delete the early boundary of the time-frame for prior notice. If a prior notice is given earlier than five days before importation it should be possible for FDA to store this information in its databases and retrieve it when needed.

- Having said this, we would like to stress, that for control purposes it should be sufficient to receive the same data that US Customs receive from the importer. Any extra information required by FDA does not enhance trade flow security. Indeed the FDA is calling for considerably more information than is actually necessary; for practical reasons, it is impossible to include the FDA registration numbers for all operators that have handled the food to be imported in the prior notice; in addition, it is difficult to see why this information should be necessary for all shipments; in case of a risk related to food imports, the proposed requirement to keep records suppliers / customers ("one up-one down") should be sufficient.

- Also, the classification of food that the FDA requires not only differs in part from Customs classifications but is also more detailed. For practical reasons, the product code to be submitted should be the customs code, not the FDA code.

- FDA proposes a definition of “originating country” that is not the same in all respects as the definition of “country of origin” for Customs Services purposes. Employing a different definition under prior notice will engender confusion and create an apparent inconsistency between prior notice filings and Customs entry documents. Operators will have an almost impossible task of keeping the nuances of the two definitions in mind as they complete the required notices and filings for the Customs Service and for FDA. BVE urges FDA to use the Customs Service definition of “country of origin” in the prior notice final regulation.

- Again, we are concerned about the treatment of samples under the Prior notice regulations. Clarification is requested on whether shipments of small quantities for market-testing or tasting will be permitted without being subject to Prior notice requirements.

- On the sanction regime, although under the proposed rule the purchaser, owner, importer or consignee would be responsible for the correct implementation of the rules, ultimately the exporter will bear the economic consequences of a detention of the products; moreover, exporters will be subjected to sanctions even though the same data will be available in another agency, namely Customs

- As already stated in connection with registration of food facilities, in order to get the system operational without disrupting trade flows, operators who supply inadequate or incomplete information should be exempt from prosecution for a defined period after implementation.